NUTRIENT ADVISORS

Follow-Up Report for the Saunders County Board of Supervisors

RE: Conditional Use Permit Application #9214 for Kevin Buse/Champion Feeders, LLC.

Kevin Buse/Champion Feeders and Mead Cattle Company have completed the directives from the Saunders County Board of Supervisors. These action steps were given at the April 13, 2021 meeting. The following is a report of findings as well as proposed and agreeable conditions for Kevin Buse/Champion Feeders.

1. Communicate with the Lower Platte North NRD in regard to phase area controls and Nitrogen management for Mead Cattle Company

   Response: I met with Daryl Andersen (Water Resource Manager) on May 11, 2021. We did confirm that the feedlot and the land application areas of manure are within the Phase 1 control area of the NRD. One requirement is the completion of the Nitrogen and water management certification. Brad Youngers, assistant manager at Mead Cattle Company has completed that certification.

   I provided Daryl with all of the historic results of the required groundwater monitoring at Mead Cattle Company. These monitoring results show that nitrates are trending lower in the feedlots monitoring wells. I also provided Daryl with a copy of the effluent distribution plan for Mead Cattle Company for his records. We discussed the process of soil sampling and nutrient budgeting on all of the manure application fields and I did send Daryl a copy of the soil sample results of the one field that is owned by Mead Cattle Company.

   We also discussed the UNMC study that will be conducted and Daryl was glad to hear that Kevin Buse has agreed to cooperate (within reason) with UNMC on this study.

   Daryl confirmed that Mead Cattle Company is currently in compliance with all LPNNRD programs we mutually agreed to communicate and cooperate to protect both surface and groundwater in and around Mead Cattle Company into the future.

2. Test Manure and Water at the Feedlot for levels of pesticides that are of concern from AltEn.

   Response: We conducted this sampling event on April 19, 2021. Mead Cattle Company invited Doris Karloff (Saunders County Board Chair) and Joseph Sisco (Midwest Laboratories Representative) to witness the sampling event.

Also present were Buck Wehrbein (Mead Cattle Manager) and Andy Scholting (Nutrient Advisors). The sample technician was Lyle Kreikemeier of Nutrient Advisors.

Potential sample points were discussed collectively and Chairwoman Karloff and Buck agreed to sample well water at two separate points and the manure from three separate points. The water was sampled from the pipeline near the livestock well northeast of the feedlot and the other sample point was directly out of the water tank in a cattle pen in Barn H. The manure was sampled from two completely separate earthen manure storage structures #8 and #9. These structures had most recently received new manure from multiple barns at the feedlot and were the best representation of the entire feedlot. The third manure sample was taken directly out of the underfloor pit in Barn H.

Sample results are included in this report. The well water sample results show ND (non-detect) for all of the chemicals in the sample package which include the pesticides of concern from AltEn as well as others in the test package. The 3 manure samples each showed trace amounts of glyphosate (common name-Roundup). To be clear, the treated seeds utilized at the AltEn, LLC, ethanol plant did not contain glyphosate. Therefore, the presence of extremely low levels of glyphosate in each manure sample is not in any way, shape or form related to AltEn It is very common to find trace levels of glyphosate in feedstuffs since a large majority of all crops grown are roundup ready and are sprayed with glyphosate. Therefore, it is also common to expect trace levels of glyphosate in manure since the livestock are eating feedstuffs from crops sprayed with glyphosate.

The only other trace was a detection of thiamethoxam at <5 ppb in the manure sample from Barn H. 5 ppb is the detection limit and therefore any levels less than that are considered to be non-quantifiable levels to report with any confidence. Thiamethoxam is an active ingredient in seed treatments as well as many household and turf type of insecticides. It is also common to find trace levels in corn and corn forage since it is used as a corn seed treatment (Ex. 4 CBI brand products). Thiamethoxam is a systemic insecticide, which means it is absorbed quickly by plants and transported to all of its parts. Therefore, it is common to find trace levels of thiamethoxam in corn residues and then the manure of the animals that consume those corn residues. Again, only one manure sample detected any thiamethoxam and it was reported as less than the detection limit.

I have included the lab analysis, methods, and submittal forms of all 5 samples. In addition, I have provided pages from the EPA federal register that identify pesticide tolerance levels for both glyphosate and thiamethoxam in corn residues. In addition, we have provided the National Primary Drinking Water Regulations

from EPA that identifies tolerance levels of pesticides including glyphosate. EPA does not have a drinking water standard for thiamethoxam so we have included the drinking water standards from the state of Minnesota Health Department which is one of few states that have established drinking water tolerance levels for thiamethoxam.

We have summarized all of this data in a simple table which is the first page of the supporting documentation. You will find that the levels of glyphosate found in the manure are nowhere close to even the levels that are acceptable in drinking water. I would also point out that the lab analysis is reporting detectable levels in part per billion (ppb). Most of the regulatory standards are in ppm or Mg/L. We have completed the conversions in the summary table so that you can review in common units.

3. Cooperate with UNMC in their study of environmental/health impact from AltEn.

   Response: Kevin Buse/Champion Feeders is and will continue to be willing to cooperate with UNMC within reasonable consideration to cost, time, and business confidentiality. Kevin, Buck, and/or their associates have not been contacted by UNMC as of the date of this report.

4. Other existing and/or proposed conditions that are agreeable to Kevin Buse/Champion Feeders.

   1. Lagoon system shall be approved by NDEE and shall have enough storage capacity for 360 days in order to assure the Saunders county public that the spreading of manure will only be done when weather and crops allow

   2. Incorporation (disc or knifing) immediately (within 24 hours of spreading) on any property on which the manure is spread. The responsibility of the incorporation of the manure remains with Champion Feeders whether they spread or whether they sell the product to a private individual.

   3. Number of animals not to exceed 30,000 head in which 90% must be under roof

   4. Screening feedlot with cedar and/or spruce trees

   5. Annually notify inhabitants within ¼ mile of potential manure application sites near them.

6. Annual compliance review with inspection by Saunders County Zoning Department

7. Feedlot maintain and adequate closure plan that is approved by NDEE

8. Failure to meet any of these conditions could result in the revocation of this permit.

Please let us know if you have any questions regarding this summary or the supporting information provided. We look forward to working Saunders county and Champion Feeders.

Respectfully submitted to the Saunders County Board of Supervisors,

Andrew Scholting

President, Nutrient Advisors

Sample ID	Glyphosate				Thiamethoxam			
	Result as Reported in ppb	*Result converted to ppm*	*Residue Tolerance in Field Corn Forage [CFR Title 40] [1] in ppm*	*EPA [2] MCL for Drinking Water [3] in ppm*	*Result as Reported in ppb*	*Result converted to ppm*	*Residue Tolerance in Field Corn Forage [CFR Title 40] [1] in ppm*	*MDH Guidance Value [4] in ppb*
21PE003094 Manure BH 4/21-1	20.40	0.020	13.00	0.70	N.D.	N.D.	0.10	200.00
21PE003096 Manure Cell 9 4/21-1	8.70	0.009	13.00	0.70	N.D.	N.D.	0.10	200.00
21PE003098 Manure Cell 8 4/21-1	10.10	0.010	13.00	0.70	<5	<.005	0.10	200.00
21PE003099 Water MCC Tank 4/21	N.D.	N.D.	13.00	0.70	N.D.	N.D.	0.10	200.00
21PE003100 Water MCC Well 4/21	N.D.	N.D.	13.00	0.70	N.D.	N.D.	0.10	200.00

[1]CFR (Code of Federal Regulations)

[2]EPA (Environmental Protection Agency)

[3]MCL (Maximum Containment Level) is an enforceable standard of the highest level of a contaminant allowed.

[4]EPA has not established guidelines for Thiamethoxam in drinking water. MDH (Minnesota Department of Health) has and states that "a person drinking water at or below the guidance value would have little or no risk for health effects"

5The detection limit for Thiamethoxam in the manure material was 5ppb. Any detection below 5ppb is considered unable to quantitatively report with confidence.

Performed By:
South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings,South Dakota 57006
Phone: 605-692-7325
E-Mail: regina.wixon@sdaglabs.com

Collected By:
Nutrient Advisors
449 E Deere St
West Point ,NE 68788
Phone: 402-372-2236
E-Mail: records@nutrientadvisors.com

Report Date: 2021-04-28

South Dakota Agricultural Laboratories has examined the sample of

Limfinite Package Id :	20210422-001
Lab Sample Id :	21PE003094
Customer Sample Id :	BH 4/21-1
Sample Description :	Manure
Date Collected :	
Date Received :	2021-04-22

RESULTS

ANALYTE	UNIT	AS RECEIVED	DETECTION LIMIT	METHOD	DATE OF EXTRACTION	DATE OF ANALYSIS
Acetamiprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Azoxystrobin	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Clothianidin	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Dinotefuran	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Glyphosate	ppb	20.4	10	LC-MS/MS	2021-04-22	2021-04-27
Imidacloprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Nitenpyram	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Thiabendazole	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Thiacloprid	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23
Thiamethoxam	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-23

QUALITY ASSURANCE

ANALYTE	UNIT	DUPLICATE	SPIKE RECOVERY	MATRIX BLANK	PROCESS BLANK	INSTRUMENT BLANK
Acetamiprid	ppb	21PE003096	94.4	ND	ND	ND
Azoxystrobin	ppb	21PE003093	95.7	ND	ND	ND
Clothianidin	ppb	21PE003096	106	ND	ND	ND
Dinotefuran	ppb	21PE003096	106	ND	ND	ND
Glyphosate	ppb	21PE003093	102	ND	ND	ND
Imidacloprid	ppb	21PE003096	122	ND	ND	ND
Nitenpyram	ppb	21PE003096	129	ND	ND	ND
Thiabendazole	ppb	21PE003093	86.6	ND	ND	ND
Thiacloprid	ppb	21PE003096	96.9	ND	ND	ND
Thiamethoxam	ppb	21PE003096	114	ND	ND	ND

Comments:

Definitions:

ppb - parts per billion

Detection Limit - Lowest concentration that can be quantitatively reported with confidence

ND - Not Detected above the limit of quantification

Duplicate - Concentration found in repeat sample analysis

Spike Recovery - Recovery based on a known amount of active ingredient spiked into a similar-matrix, blank sample

Matrix Blank - A similar-matrix, blank sample is evaluated

Process Blank - A sample without any matrix (soil, vegetation etc) is processed through the sample analysis procedure

Instrument Blank - Injection solvent is run to demonstrate no carryover between injections on the instrument

Reviewed and approved by Regina Wixon, Ph.D.

Submitted by the customer:

South Dakota Agricultural

Pesticide Residue Sample Submission Form

South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings, SD. 57006
(605) 692-7325

20210422-001
21PE003093-003098

Name: Nutrient Advisors *Sample ID: BH 4/21-1

Address: 449 E Deere St. City: West Point State: NE

Zip: 68788 Phone: (402) 372 - 2236 **Email: records@nutrientadvisors.com

**Sample ID must be marked clearly on the sample you submit. **Results will be emailed to the provided email address.*

Billing Information: ☒ Check box if billing is the same as the customer information

Name: Address:

City: State: Zip:

Phone: ( ) - Email:

Individual tests are $162 each, unless otherwise marked. Scans are $212 and include all of the compounds in a particular category. Acceptable samples include Vegetation, Water or Soil. Call to confirm other substrates.

Thank you for choosing South Dakota Agricultural Labs! We do add analytes to our testing regiment throughout the year. If a chemical of interest is not listed, please call us:
(605) 692-7325.

How much sample should you send?

Please send 30g of vegetation or 100g of soil to run an individual test. What does this look like? For vegetation, it would be about a quart sized bag packed full. If more than one test is required, please fill a gallon sized bag. For soil samples, please send 2 cups, if more than one test is required send 4 cups.

Analyses offered

Please turn page over to view the current pesticide analyses.

If you are interested in a screen of active ingredients, please check the box next to the **bold-faced** heading. This will include all active ingredients within the PGR screen for $212.

Example: PGR Screen ☑

If you are interested in single analyses, please circle the active ingredients. The cost of each individual analyte is $162 unless otherwise marked.

Example: (Mesotrione)

RUSH

Performed By:
South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings,South Dakota 57006
Phone: 605-692-7325
E-Mail: regina.wixon@sdaglabs.com

Collected By:
Nutrient Advisors
449 E Deere St
West Point ,NE 68788
Phone: 402-372-2236
E-Mail: records@nutrientadvisors.com

Report Date: 2021-04-28

South Dakota Agricultural Laboratories has examined the sample of

Limfinite Package Id :	20210422-001
Lab Sample Id :	21PE003096
Customer Sample Id :	Cell 9 4/21-1
Sample Description :	Manure
Date Collected :	
Date Received :	2021-04-22

RESULTS

ANALYTE	UNIT	AS RECEIVED	DETECTION LIMIT	METHOD	DATE OF EXTRACTION	DATE OF ANALYSIS
Acetamiprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Azoxystrobin	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Clothianidin	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Dinotefuran	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Glyphosate	ppb	<10	10	LC-MS/MS	2021-04-22	2021-04-27
Imidacloprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Nitenpyram	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Thiabendazole	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Thiacloprid	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23
Thiamethoxam	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-23

QUALITY ASSURANCE

ANALYTE	UNIT	DUPLICATE	SPIKE RECOVERY	MATRIX BLANK	PROCESS BLANK	INSTRUMENT BLANK
Acetamiprid	ppb	ND	94.4	ND	ND	ND
Azoxystrobin	ppb	21PE003093	95.7	ND	ND	ND
Clothianidin	ppb	ND	106	ND	ND	ND
Dinotefuran	ppb	ND	106	ND	ND	ND
Glyphosate	ppb	21PE003093	102	ND	ND	ND
Imidacloprid	ppb	ND	122	ND	ND	ND
Nitenpyram	ppb	ND	129	ND	ND	ND
Thiabendazole	ppb	21PE003093	86.6	ND	ND	ND
Thiacloprid	ppb	ND	96.9	ND	ND	ND
Thiamethoxam	ppb	ND	114	ND	ND	ND

Comments:

Definitions:

ppb - parts per billion

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Instrument Blank - Injection solvent is run to demonstrate no carryover between injections on the instrument

Reviewed and approved by Regina Wixon, Ph.D.

Submitted by the customer:

South Dakota Agricultural

Pesticide Residue Sample Submission Form

South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings, SD. 57006
(605) 692-7325

20210422-001
21PE003093-003098

Name: Nutrient Advisors *Sample ID: Cell 9 4/21-1

Address: 449 E Deere St. City: West Point State: NE

Zip: 68788 Phone: (402) 372 - 2236 **Email: records@nutrientadvisors.com

**Sample ID must be marked clearly on the sample you submit. **Results will be emailed to the provided email address.*

Billing Information: ☒ Check box if billing is the same as the customer information

Name: Address:

City: State: Zip:

Phone: ( ) - Email:

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Example: PGR Screen ☑

If you are interested in single analyses, please circle the active ingredients. The cost of each individual analyte is $162 unless otherwise marked.

Example: (Mesotrione)

RUSH

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E-Mail: regina.wixon@sdaglabs.com

Collected By:
Nutrient Advisors
449 E Deere St
West Point ,NE 68788
Phone: 402-372-2236
E-Mail: records@nutrientadvisors.com

Report Date: 2021-04-28

South Dakota Agricultural Laboratories has examined the sample of

Limfinite Package Id :	20210422-001
Lab Sample Id :	21PE003098
Customer Sample Id :	Cell 8 4/21-1
Sample Description :	Manure
Date Collected :	
Date Received :	2021-04-22

RESULTS

ANALYTE	UNIT	AS RECEIVED	DETECTION LIMIT	METHOD	DATE OF EXTRACTION	DATE OF ANALYSIS
Acetamiprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Azoxystrobin	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Clothianidin	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Dinotefuran	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Glyphosate	ppb	10.1	10	LC-MS/MS	2021-04-22	2021-04-27
Imidacloprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Nitenpyram	ppb	ND	7	LC-MS/MS	2021-04-23	2021-04-23
Thiabendazole	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-26
Thiacloprid	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23
Thiamethoxam	ppb	<5	5	LC-MS/MS	2021-04-23	2021-04-23

QUALITY ASSURANCE

ANALYTE	UNIT	DUPLICATE	SPIKE RECOVERY	MATRIX BLANK	PROCESS BLANK	INSTRUMENT BLANK
Acetamiprid	ppb	21PE003096	94.4	ND	ND	ND
Azoxystrobin	ppb	21PE003093	95.7	ND	ND	ND
Clothianidin	ppb	21PE003096	106	ND	ND	ND
Dinotefuran	ppb	21PE003096	106	ND	ND	ND
Glyphosate	ppb	21PE003093	102	ND	ND	ND
Imidacloprid	ppb	21PE003096	122	ND	ND	ND
Nitenpyram	ppb	21PE003096	129	ND	ND	ND
Thiabendazole	ppb	21PE003093	86.6	ND	ND	ND
Thiacloprid	ppb	21PE003096	96.9	ND	ND	ND
Thiamethoxam	ppb	21PE003096	114	ND	ND	ND

Comments:

Definitions:

ppb - parts per billion

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Instrument Blank - Injection solvent is run to demonstrate no carryover between injections on the instrument

Reviewed and approved by Regina Wixon, Ph.D.

Submitted by the customer:

South Dakota Agricultural

Pesticide Residue Sample Submission Form

South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings, SD. 57006
(605) 692-7325

20210422-001
21PE003093-003098

Name: Nutrient Advisors *Sample ID: Cell 8 4/21-1

Address: 449 E Deere St. City: West Point State: NE

Zip: 68788 Phone: (402) 372 - 2236 **Email: records@nutrientadvisors.com

**Sample ID must be marked clearly on the sample you submit. **Results will be emailed to the provided email address.*

Billing Information: ☒ Check box if billing is the same as the customer information

Name: Address:

City: State: Zip:

Phone: ( ) - Email:

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Example: PGR Screen ☑

If you are interested in single analyses, please circle the active ingredients. The cost of each individual analyte is $162 unless otherwise marked.

Example: (Mesotrione)

RUSH

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1335 Western Avenue
Brookings,South Dakota 57006
Phone: 605-692-7325
E-Mail: regina.wixon@sdaglabs.com

Collected By:
Nutrient Advisors
449 E Deere St
West Point ,NE 68788
Phone: 402-372-2236
E-Mail: records@nutrientadvisors.com

Report Date: 2021-04-28

South Dakota Agricultural Laboratories has examined the sample of

Limfinite Package Id :	20210422-002
Lab Sample Id :	21PE003099
Customer Sample Id :	MCC Tank 4/21
Sample Description :	Water
Date Collected :	
Date Received :	2021-04-22

RESULTS

ANALYTE	UNIT	AS RECEIVED	DETECTION LIMIT	METHOD	DATE OF EXTRACTION	DATE OF ANALYSIS
Acetamprid	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23
Azoxystrobin	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-26
Clothianidin	ppb	ND	8	LC-MS/MS	2021-04-23	2021-04-23
Dinotefuron	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Glyphosate	ppb	ND	10	LC-MS/MS	2021-04-22	2021-04-27
Imidacloprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Nitenpyram	ppb	ND	8	LC-MS/MS	2021-04-23	2021-04-23
Thiabendazole	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-25
Thiacloprid	ppb	ND	6	LC-MS/MS	2021-04-23	2021-04-23
Thiamethoxam	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23

QUALITY ASSURANCE

ANALYTE	UNIT	DUPLICATE	SPIKE RECOVERY	MATRIX BLANK	PROCESS BLANK	INSTRUMENT BLANK
Acetamprid	ppb	21PE003078	113	ND	ND	ND
Azoxystrobin	ppb	21PE002959	102	ND	ND	ND
Clothianidin	ppb	21PE003078	115	ND	ND	ND
Dinotefuron	ppb	21PE003078	108	ND	ND	ND
Glyphosate	ppb	21PE002959	96.5	ND	ND	ND
Imidacloprid	ppb	21PE003078	122	ND	ND	ND
Nitenpyram	ppb	21PE003078	110	ND	ND	ND
Thiabendazole	ppb	21PE002959	105	ND	ND	ND
Thiacloprid	ppb	21PE003078	114	ND	ND	ND
Thiamethoxam	ppb	21PE003078	110	ND	ND	ND

Comments:

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BRIEF METHOD DESCRIPTION

Neonicotinoids in soil, water and vegetation - Purpose and Scope

Neonicotinoids are a class of neuro-active insecticides chemically similar to nicotine. The limits of detection for the neonicotinoids are 1 ppb for limit of detection and 5 ppb for limit of quantitation.

Neonicotinoids in soil, water and vegetation - References

J. Klein and L. Alder, JAOACI 86(5): 101501037 (2003)

Neonicotinoids in soil, water and vegetation - Basic Principles

Neonicotinoids are fairly polar and are extracted with aqueous acetonitrile, filtered and prepared for LC-MS/MS analysis.

Reviewed and approved by Regina Wixon, Ph.D.

Submitted by the customer:

South Dakota Agricultural

Pesticide Residue Sample Submission Form

South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings, SD. 57006
(605) 692-7325

20210422-002
21PE003099-003100

20210422-002
21PE003099-3100

Name: Nutrient Advisors *Sample ID: MCC Tank 4/21

Address: 449 E Deere St. City: West Point State: NE

Zip: 68788 Phone: (402) 372 - 2236 **Email: records@nutrientadvisors.com

**Sample ID must be marked clearly on the sample you submit. **Results will be emailed to the provided email address.*

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City: _____ State: _____ Zip: _____

Phone: (____) _____ - _____ Email: _____

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(605) 692-7325.

How much sample should you send?

Please send 30g of vegetation or 100g of soil to run an individual test. What does this look like? For vegetation, it would be about a quart sized bag packed full. If more than one test is required, please fill a gallon sized bag. For soil samples, please send 2 cups, if more than one test is required send 4 cups.

Analyses offered

Please turn page over to view the current pesticide analyses.

If you are interested in a screen of active ingredients, please check the box next to the **bold-faced** heading. This will include all active ingredients within the PGR screen for $212.

Example: PGR Screen ☑

If you are interested in single analyses, please circle the active ingredients. The cost of each individual analyte is $162 unless otherwise marked.

Example: (Mesotrione)

RUSH

Sample(s) Received at SD Ag Labs
Date 2021.04.22
Received by
Alyssa Kennedy

Performed By:
South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings,South Dakota 57006
Phone: 605-692-7325
E-Mail: regina.wixon@sdaglabs.com

Collected By:
Nutrient Advisors
449 E Deere St
West Point ,NE 68788
Phone: 402-372-2236
E-Mail: records@nutrientadvisors.com

Report Date: 2021-04-28

South Dakota Agricultural Laboratories has examined the sample of

Limfinite Package Id :	20210422-002
Lab Sample Id :	21PE003100
Customer Sample Id :	MCC Well 4/21
Sample Description :	Water
Date Collected :	
Date Received :	2021-04-22

RESULTS

ANALYTE	UNIT	AS RECEIVED	DETECTION LIMIT	METHOD	DATE OF EXTRACTION	DATE OF ANALYSIS
Acetamprid	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23
Azoxystrobin	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-26
Clothianidin	ppb	ND	8	LC-MS/MS	2021-04-23	2021-04-23
Dinotefuron	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Glyphosate	ppb	ND	10	LC-MS/MS	2021-04-22	2021-04-27
Imidacloprid	ppb	ND	4	LC-MS/MS	2021-04-23	2021-04-23
Nitenpyram	ppb	ND	8	LC-MS/MS	2021-04-23	2021-04-23
Thiabendazole	ppb	ND	5	LC-MS/MS	2021-04-23	2021-04-25
Thiacloprid	ppb	ND	6	LC-MS/MS	2021-04-23	2021-04-23
Thiamethoxam	ppb	ND	3	LC-MS/MS	2021-04-23	2021-04-23

QUALITY ASSURANCE

ANALYTE	UNIT	DUPLICATE	SPIKE RECOVERY	MATRIX BLANK	PROCESS BLANK	INSTRUMENT BLANK
Acetamprid	ppb	21PE003078	113	ND	ND	ND
Azoxystrobin	ppb	21PE002959	102	ND	ND	ND
Clothianidin	ppb	21PE003078	115	ND	ND	ND
Dinotefuron	ppb	21PE003078	108	ND	ND	ND
Glyphosate	ppb	21PE002959	96.5	ND	ND	ND
Imidacloprid	ppb	21PE003078	122	ND	ND	ND
Nitenpyram	ppb	21PE003078	110	ND	ND	ND
Thiabendazole	ppb	21PE002959	105	ND	ND	ND
Thiacloprid	ppb	21PE003078	114	ND	ND	ND
Thiamethoxam	ppb	21PE003078	110	ND	ND	ND

Comments:

Definitions:

ppb - parts per billion

Detection Limit - Lowest concentration that can be quantitatively reported with confidence

ND - Not Detected above the limit of quantification

Duplicate - Concentration found in repeat sample analysis

Spike Recovery - Recovery based on a known amount of active ingredient spiked into a similar-matrix, blank sample

Matrix Blank - A similar-matrix, blank sample is evaluated

Process Blank - A sample without any matrix (soil, vegetation etc) is processed through the sample analysis procedure

Instrument Blank - Injection solvent is run to demonstrate no carryover between injections on the instrument

BRIEF METHOD DESCRIPTION

Neonicotinoids in soil, water and vegetation - Purpose and Scope

Neonicotinoids are a class of neuro-active insecticides chemically similar to nicotine. The limits of detection for the neonicotinoids are 1 ppb for limit of detection and 5 ppb for limit of quantitation.

Neonicotinoids in soil, water and vegetation - References

J. Klein and L. Alder, JAOACI 86(5): 101501037 (2003)

Neonicotinoids in soil, water and vegetation - Basic Principles

Neonicotinoids are fairly polar and are extracted with aqueous acetonitrile, filtered and prepared for LC-MS/MS analysis.

Reviewed and approved by Regina Wixon, Ph.D.

Submitted by the customer:

South Dakota Agricultural

Pesticide Residue Sample Submission Form

South Dakota Agricultural Laboratories
1335 Western Avenue
Brookings, SD. 57006
(605) 692-7325

20210422-002
21PE003099-003100

Name: Nutrient Advisors *Sample ID: MCC Well 4/21

Address: 449 E Deere St. City: West Point State: NE

Zip: 68788 Phone: (402) 372 - 2236 **Email: records@nutrientadvisors.com

**Sample ID must be marked clearly on the sample you submit. **Results will be emailed to the provided email address.*

Billing Information: ☒ Check box if billing is the same as the customer information

Name: Address:

City: State: Zip:

Phone: ( ) - Email:

Individual tests are $162 each, unless otherwise marked. Scans are $212 and include all of the compounds in a particular category. Acceptable samples include Vegetation, Water or Soil. Call to confirm other substrates.

Thank you for choosing South Dakota Agricultural Labs! We do add analytes to our testing regiment throughout the year. If a chemical of interest is not listed, please call us:
(605) 692-7325.

How much sample should you send?

Please send 30g of vegetation or 100g of soil to run an individual test. What does this look like? For vegetation, it would be about a quart sized bag packed full. If more than one test is required, please fill a gallon sized bag. For soil samples, please send 2 cups, if more than one test is required send 4 cups.

Analyses offered

Please turn page over to view the current pesticide analyses.

If you are interested in a screen of active ingredients, please check the box next to the **bold-faced** heading. This will include all active ingredients within the PGR screen for $212.

Example: PGR Screen ☑

If you are interested in single analyses, please circle the active ingredients. The cost of each individual analyte is $162 unless otherwise marked.

Example: (Mesotrione)

RUSH

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 2, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Amend § 180.434 as follows:

■ i. In the table to paragraph (a), remove the entries for "berry group 13," "onion, bulb," "onion, green," and "strawberry"; revise the entries for "peppermint, tops" and "spearmint, tops", and add alphabetically entries for "bushberry, subgroup 13–07B," "caneberry, subgroup 13–07A," "low growing berry subgroup 13–07G, except cranberry," "onion, bulb subgroup 3–07A," and "onion, green, subgroup 3–07B."

■ ii. In the table to paragraph (b) add alphabetically and entry for "avocado."

The added and revised text reads as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Bushberry, subgroup 13–07B ...	1.0
Caneberry, subgroup 13–07A ..	1.0
* * * * *	
Low growing berry subgroup 13–07G, except cranberry	1.3
* * * * *	
Onion, bulb subgroup 3–07A ...	0.2
Onion, green, subgroup 3–07B	9.0
* * * * *	
Peppermint, tops	10.0
* * * * *	
Spearmint, tops	10.0
* * * * *	

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Avocado	10	12/31/13
* * * * *		

* * * * *

[FR Doc. 2011–11564 Filed 5–10–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0938; FRL–8872–6]

[redacted]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases the established tolerance for residues of glyphosate in or on corn, field, forage. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–

OPP–2010–0938. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0938 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 11, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0938, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 4, 2011 (76 FR 6465) (FRL–8858–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7741) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20052. The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, *N*-(phosphonomethyl) glycine, in or on corn, field, forage at 13 parts per million (ppm). That notice referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glyphosate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate follows.

In the **Federal Register** of April 8, 2011 (76 FR 19701) (FRL–8866–8), EPA issued a final rule establishing a tolerance for residues of glyphosate in or on sweet corn and reducing the established tolerance for residues of glyphosate and *N*-acetyl-glyphosate in or on poultry meat. When the Agency conducted the risk assessment in

support of the April 8, 2011 tolerance action, it considered secondary residues of glyphosate in livestock commodities from consumption of glyphosate-treated feed items, including corn forage. The Agency has determined that increasing the tolerance on corn forage from 6 ppm to 13 ppm will not increase residues of glyphosate in livestock commodities above those assumed in the previous risk assessment. The livestock dietary burdens for glyphosate were calculated assuming the roughage portion of the diet for beef and dairy cattle consisted of nongrass animal feed and grass forage, which have much higher tolerances (400 and 300 ppm, respectively) than corn forage. Therefore, increasing the tolerance for corn forage from 6 to 13 ppm will not affect the estimated livestock dietary burden or expected residues of glyphosate in livestock commodities and will not change the estimated aggregate risks resulting from use of glyphosate, as discussed in the April 8, 2011 (76 FR 19701; FRL–8866–8) **Federal Register**. Refer to the **Federal Register** document, available at *http://www.regulations.gov,* for a detailed discussion of the aggregate risk assessment and determination of safety.

Therefore, based on the risk assessment discussed in the final rule published in the **Federal Register** of April 8, 2011 (76 FR 19701; FRL–8866–8) EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC) equipped with a fluorescence detector method; LOQ = 0.05 ppm) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for residues of glyphosate in or on maize at 5 ppm. The MRL for maize would cover residues of glyphosate on corn (maize) forage. This MRL is different than the tolerance being established for glyphosate on field corn forage in the United States due to differences in Codex and U.S. residue definitions. The U.S. tolerance of 13 ppm for corn, field, forage is necessarily higher than the Codex MRL to account for residues of both glyphosate and its metabolite N-acetyl glyphosate. N-acetyl glyphosate is found in genetically modified (GMO) glyphosate-resistant commodities, including corn, grown in the U.S. Therefore, it is included in the U.S. tolerance but not the Codex expression, accounting for the difference in the established MRLs.

C. Response to Comments

EPA received comments from two individuals expressing concerns about pesticides generally and objecting to the presence of any pesticide residues in food. The Agency understands the commenters' concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The submitted comments appear to be directed at the underlying statute and not EPA's implementation of it; the commenters made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Monsanto Company proposed a tolerance for residues of glyphosate on corn, field, forage at 13 ppm. The current tolerance is expressed in terms of glyphosate, including its metabolites and degradates; and compliance with the tolerance level is determined by measuring glyphosate and its N-acetyl-glyphosate metabolite. EPA is increasing the tolerance level from 6 ppm to 13 ppm, as proposed, but is retaining the current tolerance expression to clarify the chemical moieties that are covered by the tolerance and specify how compliance with the tolerance is to be measured.

V. Conclusion

Therefore, the previously established tolerance for residues of glyphosate, including its metabolites and degradates, in or on corn, field, forage is amended as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal

governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 2, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.364 is amended by revising the following entry in the table in paragraph (a)(2) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) * * *

* * * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Corn, field, forage	
* * * * *	

* * * * *

[FR Doc. 2011–11205 Filed 5–10–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2009–0187; FRL–8874–2]

RIN 2070–AJ43

TSCA Inventory Update Reporting Modifications; Submission Period Suspension

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) regulations by suspending the next IUR submission period. The IUR requires manufacturers (including importers) of certain chemical substances included on the TSCA Chemical Substance Inventory (TSCA Inventory) to report current data on the manufacturing, processing, and use of the chemical substances. In the **Federal Register** of August 13, 2010, EPA published proposed modifications to the IUR regulations. EPA is suspending the next submission period to allow additional time to finalize the proposed modifications to the IUR regulations, and to avoid finalizing changes to the reporting requirements in the midst of the 2011 submission period. EPA expects to finalize, in the near future, changes to the IUR reporting requirements which will supersede this action.

DATES: This final rule is effective May 11, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2009–0187. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Chenise Farquharson, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–7768; e-mail address: *farquharson.chenise@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including manufacture as a byproduct) or import chemical substances listed on the TSCA Inventory. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers and importers (NAICS codes 325 and 324110; *e.g.,* chemical manufacturing and processing and petroleum refineries).
- Chemical users and processors who may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344; *e.g.,* utilities, paper manufacturing, primary metal

National Primary Drinking Water Regulations

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Acrylamide	TT[4]	Nervous system or blood problems; increased risk of cancer	Added to water during sewage/ wastewater treatment	**zero**
Alachlor	0.002	Eye, liver, kidney, or spleen problems; anemia; increased risk of cancer	Runoff from herbicide used on row crops	**zero**
Alpha/photon emitters	15 picocuries per Liter (pCi/L)	Increased risk of cancer	Erosion of natural deposits of certain minerals that are radioactive and may emit a form of radiation known as alpha radiation	**zero**
Antimony	0.006	Increase in blood cholesterol; decrease in blood sugar	Discharge from petroleum refineries; fire retardants; ceramics; electronics; solder	**0.006**
Arsenic	0.010	Skin damage or problems with circulatory systems, and may have increased risk of getting cancer	Erosion of natural deposits; runoff from orchards; runoff from glass & electronics production wastes	**0**
Asbestos (fibers >10 micrometers)	7 million fibers per Liter (MFL)	Increased risk of developing benign intestinal polyps	Decay of asbestos cement in water mains; erosion of natural deposits	**7 MFL**
Atrazine	0.003	Cardiovascular system or reproductive problems	Runoff from herbicide used on row crops	**0.003**
Barium	2	Increase in blood pressure	Discharge of drilling wastes; discharge from metal refineries; erosion of natural deposits	**2**
Benzene	0.005	Anemia; decrease in blood platelets; increased risk of cancer	Discharge from factories; leaching from gas storage tanks and landfills	**zero**
Benzo(a)pyrene (PAHs)	0.0002	Reproductive difficulties; increased risk of cancer	Leaching from linings of water storage tanks and distribution lines	**zero**
Beryllium	0.004	Intestinal lesions	Discharge from metal refineries and coal-burning factories; discharge from electrical, aerospace, and defense industries	**0.004**
Beta photon emitters	4 millirems per year	Increased risk of cancer	Decay of natural and man-made deposits of certain minerals that are radioactive and may emit forms of radiation known as photons and beta radiation	**zero**
Bromate	0.010	Increased risk of cancer	Byproduct of drinking water disinfection	**zero**
Cadmium	0.005	Kidney damage	Corrosion of galvanized pipes; erosion of natural deposits; discharge from metal refineries; runoff from waste batteries and paints	**0.005**
Carbofuran	0.04	Problems with blood, nervous system, or reproductive system	Leaching of soil fumigant used on rice and alfalfa	**0.04**

LEGEND

DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Carbon tetrachloride	0.005	Liver problems; increased risk of cancer	Discharge from chemical plants and other industrial activities	**zero**
Chloramines (as Cl_2)	MRDL=4.0[1]	Eye/nose irritation; stomach discomfort; anemia	Water additive used to control microbes	**MRDLG=4[1]**
Chlordane	0.002	Liver or nervous system problems; increased risk of cancer	Residue of banned termiticide	**zero**
Chlorine (as Cl_2)	MRDL=4.0[1]	Eye/nose irritation; stomach discomfort	Water additive used to control microbes	**MRDLG=4[1]**
Chlorine dioxide (as ClO_2)	MRDL=0.8[1]	Anemia; infants, young children, and fetuses of pregnant women: nervous system effects	Water additive used to control microbes	**MRDLG=0.8[1]**
Chlorite	1.0	Anemia; infants, young children, and fetuses of pregnant women: nervous system effects	Byproduct of drinking water disinfection	**0.8**
Chlorobenzene	0.1	Liver or kidney problems	Discharge from chemical and agricultural chemical factories	**0.1**
Chromium (total)	0.1	Allergic dermatitis	Discharge from steel and pulp mills; erosion of natural deposits	**0.1**
Copper	TT[5]; Action Level=1.3	Short-term exposure: Gastrointestinal distress. Long-term exposure: Liver or kidney damage. People with Wilson's Disease should consult their personal doctor if the amount of copper in their water exceeds the action level	Corrosion of household plumbing systems; erosion of natural deposits	**1.3**
Cryptosporidium	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
Cyanide (as free cyanide)	0.2	Nerve damage or thyroid problems	Discharge from steel/metal factories; discharge from plastic and fertilizer factories	**0.2**
2,4-D	0.07	Kidney, liver, or adrenal gland problems	Runoff from herbicide used on row crops	**0.07**
Dalapon	0.2	Minor kidney changes	Runoff from herbicide used on rights of way	**0.2**
1,2-Dibromo-3-chloropropane (DBCP)	0.0002	Reproductive difficulties; increased risk of cancer	Runoff/leaching from soil fumigant used on soybeans, cotton, pineapples, and orchards	**zero**
o-Dichlorobenzene	0.6	Liver, kidney, or circulatory system problems	Discharge from industrial chemical factories	**0.6**
p-Dichlorobenzene	0.075	Anemia; liver, kidney, or spleen damage; changes in blood	Discharge from industrial chemical factories	**0.075**
1,2-Dichloroethane	0.005	Increased risk of cancer	Discharge from industrial chemical factories	**zero**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
1,1-Dichloroethylene	0.007	Liver problems	Discharge from industrial chemical factories	**0.007**
cis-1,2-Dichloroethylene	0.07	Liver problems	Discharge from industrial chemical factories	**0.07**
trans-1,2, Dichloroethylene	0.1	Liver problems	Discharge from industrial chemical factories	**0.1**
Dichloromethane	0.005	Liver problems; increased risk of cancer	Discharge from industrial chemical factories	**zero**
1,2-Dichloropropane	0.005	Increased risk of cancer	Discharge from industrial chemical factories	**zero**
Di(2-ethylhexyl) adipate	0.4	Weight loss, liver problems, or possible reproductive difficulties	Discharge from chemical factories	**0.4**
Di(2-ethylhexyl) phthalate	0.006	Reproductive difficulties; liver problems; increased risk of cancer	Discharge from rubber and chemical factories	**zero**
Dinoseb	0.007	Reproductive difficulties	Runoff from herbicide used on soybeans and vegetables	**0.007**
Dioxin (2,3,7,8-TCDD)	0.00000003	Reproductive difficulties; increased risk of cancer	Emissions from waste incineration and other combustion; discharge from chemical factories	**zero**
Diquat	0.02	Cataracts	Runoff from herbicide use	**0.02**
Endothall	0.1	Stomach and intestinal problems	Runoff from herbicide use	**0.1**
Endrin	0.002	Liver problems	Residue of banned insecticide	**0.002**
Epichlorohydrin	TT[4]	Increased cancer risk; stomach problems	Discharge from industrial chemical factories; an impurity of some water treatment chemicals	**zero**
Ethylbenzene	0.7	Liver or kidney problems	Discharge from petroleum refineries	**0.7**
Ethylene dibromide	0.00005	Problems with liver, stomach, reproductive system, or kidneys; increased risk of cancer	Discharge from petroleum refineries	**zero**
Fecal coliform and *E. coli*	MCL[6]	Fecal coliforms and *E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes may cause short term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, and people with severely compromised immune systems.	Human and animal fecal waste	**zero[6]**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Fluoride	4.0	Bone disease (pain and tenderness of the bones); children may get mottled teeth	Water additive which promotes strong teeth; erosion of natural deposits; discharge from fertilizer and aluminum factories	**4.0**
Giardia lamblia	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
[redacted]	[redacted]	Kidney problems; reproductive difficulties	Runoff from herbicide use	**0.7**
Haloacetic acids (HAA5)	0.060	Increased risk of cancer	Byproduct of drinking water disinfection	**n/a[9]**
Heptachlor	0.0004	Liver damage; increased risk of cancer	Residue of banned termiticide	**zero**
Heptachlor epoxide	0.0002	Liver damage; increased risk of cancer	Breakdown of heptachlor	**zero**
Heterotrophic plate count (HPC)	TT[7]	HPC has no health effects; it is an analytic method used to measure the variety of bacteria that are common in water. The lower the concentration of bacteria in drinking water, the better maintained the water system is.	HPC measures a range of bacteria that are naturally present in the environment	**n/a**
Hexachlorobenzene	0.001	Liver or kidney problems; reproductive difficulties; increased risk of cancer	Discharge from metal refineries and agricultural chemical factories	**zero**
Hexachloro-cyclopentadiene	0.05	Kidney or stomach problems	Discharge from chemical factories	**0.05**
Lead	TT[5]; Action Level=0.015	Infants and children: Delays in physical or mental development; children could show slight deficits in attention span and learning abilities; Adults: Kidney problems; high blood pressure	Corrosion of household plumbing systems; erosion of natural deposits	**zero**
Legionella	TT[7]	Legionnaire's Disease, a type of pneumonia	Found naturally in water; multiplies in heating systems	**zero**
Lindane	0.0002	Liver or kidney problems	Runoff/leaching from insecticide used on cattle, lumber, and gardens	**0.0002**
Mercury (inorganic)	0.002	Kidney damage	Erosion of natural deposits; discharge from refineries and factories; runoff from landfills and croplands	**0.002**
Methoxychlor	0.04	Reproductive difficulties	Runoff/leaching from insecticide used on fruits, vegetables, alfalfa, and livestock	**0.04**
Nitrate (measured as Nitrogen)	10	Infants below the age of six months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue-baby syndrome.	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	**10**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
Nitrite (measured as Nitrogen)	1	Infants below the age of six months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue-baby syndrome.	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	1
Oxamyl (Vydate)	0.2	Slight nervous system effects	Runoff/leaching from insecticide used on apples, potatoes, and tomatoes	0.2
Pentachlorophenol	0.001	Liver or kidney problems; increased cancer risk	Discharge from wood-preserving factories	zero
Picloram	0.5	Liver problems	Herbicide runoff	0.5
Polychlorinated biphenyls (PCBs)	0.0005	Skin changes; thymus gland problems; immune deficiencies; reproductive or nervous system difficulties; increased risk of cancer	Runoff from landfills; discharge of waste chemicals	zero
Radium 226 and Radium 228 (combined)	5 pCi/L	Increased risk of cancer	Erosion of natural deposits	zero
Selenium	0.05	Hair or fingernail loss; numbness in fingers or toes; circulatory problems	Discharge from petroleum and metal refineries; erosion of natural deposits; discharge from mines	0.05
Simazine	0.004	Problems with blood	Herbicide runoff	0.004
Styrene	0.1	Liver, kidney, or circulatory system problems	Discharge from rubber and plastic factories; leaching from landfills	0.1
Tetrachloroethylene	0.005	Liver problems; increased risk of cancer	Discharge from factories and dry cleaners	zero
Thallium	0.002	Hair loss; changes in blood; kidney, intestine, or liver problems	Leaching from ore-processing sites; discharge from electronics, glass, and drug factories	0.0005
Toluene	1	Nervous system, kidney, or liver problems	Discharge from petroleum factories	1
Total Coliforms	5.0 percent[8]	Coliforms are bacteria that indicate that other, potentially harmful bacteria may be present. See fecal coliforms and *E. coli*	Naturally present in the environment	zero
Total Trihalomethanes (TTHMs)	0.080	Liver, kidney, or central nervous system problems; increased risk of cancer	Byproduct of drinking water disinfection	n/a[9]
Toxaphene	0.003	Kidney, liver, or thyroid problems; increased risk of cancer	Runoff/leaching from insecticide used on cotton and cattle	zero
2,4,5-TP (Silvex)	0.05	Liver problems	Residue of banned herbicide	0.05
1,2,4-Trichlorobenzene	0.07	Changes in adrenal glands	Discharge from textile finishing factories	0.07

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

Contaminant	MCL or TT[1] (mg/L)[2]	Potential health effects from long-term[3] exposure above the MCL	Common sources of contaminant in drinking water	Public Health Goal (mg/L)[2]
1,1,1-Trichloroethane	0.2	Liver, nervous system, or circulatory problems	Discharge from metal degreasing sites and other factories	**0.2**
1,1,2-Trichloroethane	0.005	Liver, kidney, or immune system problems	Discharge from industrial chemical factories	**0.003**
Trichloroethylene	0.005	Liver problems; increased risk of cancer	Discharge from metal degreasing sites and other factories	**zero**
Turbidity	TT[7]	Turbidity is a measure of the cloudiness of water. It is used to indicate water quality and filtrationeffectiveness (e.g., whether disease-causing organisms are present). Higher turbidity levels are often associated with higher levels of disease-causing microorganisms such as viruses, parasites, and some bacteria. These organisms can cause short term symptoms such as nausea, cramps, diarrhea, and associated headaches.	Soil runoff	**n/a**
Uranium	30µg/L	Increased risk of cancer, kidney toxicity	Erosion of natural deposits	**zero**
Vinyl chloride	0.002	Increased risk of cancer	Leaching from PVC pipes; discharge from plastic factories	**zero**
Viruses (enteric)	TT[7]	Short-term exposure: Gastrointestinal illness (e.g., diarrhea, vomiting, cramps)	Human and animal fecal waste	**zero**
Xylenes (total)	10	Nervous system damage	Discharge from petroleum factories; discharge from chemical factories	**10**

LEGEND DISINFECTANT | DISINFECTION BYPRODUCT | INORGANIC CHEMICAL | MICROORGANISM | ORGANIC CHEMICAL | RADIONUCLIDES

NOTES

1 Definitions
- **Maximum Contaminant Level Goal (MCLG):** The level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety and are non-enforceable public health goals.
- **Maximum Contaminant Level (MCL):** The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible using the best available treatment technology and taking cost into consideration. MCLs are enforceable standards.
- **Maximum Residual Disinfectant Level Goal (MRDLG):** The level of a drinking water disinfectant below which there is no known or expected risk to health. MRDLGs do not reflectthe benefitsof the use of disinfectants to control microbial contaminants.
- **Maximum Residual Disinfectant Level (MRDL):** The highest level of a disinfectant allowed in drinking water. There is convincing evidence that addition of a disinfectant is necessary for control of microbial contaminants.
- **Treatment Technique (TT):** A required process intended to reduce the level of a contaminant in drinking water.

2 Units are in milligrams per liter (mg/L) unless otherwise noted. Milligrams per liter are equivalent to parts per million (ppm).

3 Health effects are from long-term exposure unless specifiedas short-term exposure.

4 Each water system must certify annually, in writing, to the state (using third-party or manufacturers certification)that when it uses acrylamide and/or epichlorohydrin to treat water, the combination (or product) of dose and monomer level does not exceed the levels specified,as follows: Acrylamide = 0.05 percent dosed at 1 mg/L (or equivalent); Epichlorohydrin = 0.01 percent dosed at 20 mg/L (or equivalent).

5 Lead and copper are regulated by a Treatment Technique that requires systems to control the corrosiveness of their water. If more than 10 percent of tap water samples exceed the action level, water systems must take additional steps. For copper, the action level is 1.3 mg/L, and for lead is 0.015 mg/L.

6 A routine sample that is fecal coliform-positive or E. coli-positive triggers repeat samples--if any repeat sample is total coliform-positive, the system has an acute MCL violation. A routine sample that is total coliform-positive and fecal coliform-negative or E. coli-negative triggers repeat samples--if any repeat sample is fecal coliform-positive or E. coli-positive, the system has an acute MCL violation. See also Total Coliforms.

7 EPA's surface water treatment rules require systems using surface water or ground water under the direct influenceof surface water to (1) disinfect their water, and (2) filter their water or meet criteria for avoiding filtrationso that the following contaminants are controlled at the following levels:
- ***Cryptosporidium*:** 99 percent removal for systems that filter.Unfilteredsystems are required to include Cryptosporidium in their existing watershed control provisions.
- **Giardia lamblia:** 99.9 percent removal/inactivation
- **Viruses:** 99.9 percent removal/inactivation
- ***Legionella*:** No limit, but EPA believes that if *Giardia* and viruses are removed/inactivated, according to the treatment techniques in the surface water treatment rule, *Legionella* will also be controlled.
- **Turbidity:** For systems that use conventional or direct filtration,at no time can turbidity (cloudiness of water) go higher than 1 nephelometric turbidity unit (NTU), and samples for turbidity must be less than or equal to 0.3 NTU in at least 95 percent of the samples in any month. Systems that use filtrationother than the conventional or direct filtration must follow state limits, which must include turbidity at no time exceeding 5 NTU.
- **HPC:** No more than 500 bacterial colonies per milliliter
- **Long Term 1 Enhanced Surface Water Treatment:** Surface water systems or ground water systems under the direct influenceof surface water serving fewer than 10,000 people must comply with the applicable Long Term 1 Enhanced Surface Water Treatment Rule provisions (e.g. turbidity standards, individual filtermonitoring, *Cryptosporidium* removal requirements, updated watershed control requirements for unfilteredsystems).
- **Long Term 2 Enhanced Surface Water Treatment:** This rule applies to all surface water systems or ground water systems under the direct influenceof surface water. The rule targets additional *Cryptosporidium* treatment requirements for higher risk systems and includes provisions to reduce risks from uncovered finishedwater storages facilities and to ensure that the systems maintain microbial protection as they take steps to reduce the formation of disinfection byproducts. (Monitoring start dates are staggered by system size. The largest systems (serving at least 100,000 people) will begin monitoring in October 2006 and the smallest systems (serving fewer than 10,000 people) will not begin monitoring until October 2008. After completing monitoring and determining their treatment bin, systems generally have three years to comply with any additional treatment requirements.)
- **Filter Backwash Recycling:** The Filter Backwash Recycling Rule requires systems that recycle to return specificrecycle flowsthrough all processes of the system's existing conventional or direct filtrationsystem or at an alternate location approved by the state.

8 No more than 5.0 percent samples total coliform-positive in a month. (For water systems that collect fewer than 40 routine samples per month, no more than one sample can be total coliform-positive per month.) Every sample that has total coliform must be analyzed for either fecal coliforms or E. coli. If two consecutive TC-positive samples, and one is also positive for E. coli or fecal coliforms, system has an acute MCL violation.

9 Although there is no collective MCLG for this contaminant group, there are individual MCLGs for some of the individual contaminants:
- **Haloacetic acids:** dichloroacetic acid (zero); trichloroacetic acid (0.3 mg/L)
- **Trihalomethanes:** bromodichloromethane (zero); bromoform (zero); dibromochloromethane (0.06 mg/L)

NATIONAL SECONDARY DRINKING WATER REGULATION

National Secondary Drinking Water Regulations are non-enforceable guidelines regarding contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water. EPA recommends secondary standards to water systems but does not require systems to comply. However, some states may choose to adopt them as enforceable standards.

Contaminant	Secondary Maximum Contaminant Level
Aluminum	0.05 to 0.2 mg/L
Chloride	250 mg/L
Color	15 (color units)
Copper	1.0 mg/L
Corrosivity	Noncorrosive
Fluoride	2.0 mg/L
Foaming Agents	0.5 mg/L
Iron	0.3 mg/L
Manganese	0.05 mg/L
Odor	3 threshold odor number
pH	6.5-8.5
Silver	0.10 mg/L
Sulfate	250 mg/L
Total Dissolved Solids	500 mg/L
Zinc	5 mg/L

FOR MORE INFORMATION ON EPA'S SAFE DRINKING WATER:

visit: **epa.gov/safewater**

call: **(800) 426-4791**

ADDITIONAL INFORMATION:

To order additional posters or other ground water and drinking water publications, please contact the National Service Center for Environmental Publications at: **(800) 490-9198**, or email: **nscep@bps-lmit.com**.

OFFICE OF GROUND WATER AND DRINKING WATER

the free form of its acide metabolite CG–321113 [(E,E)-(methoxyimino)-[2-[1-(3-(trifluoromethylphenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid, in or on imported coffee, green bean at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register.** This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.555 is amended by alphabetically adding the following commodity and footnote 2 to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Coffee, green bean [2]	0.02
* * * * *	

[2] There are no U.S. registrations as of January 18, 2012 for use on coffee, green bean.

* * * * *

[FR Doc. 2012–4977 Filed 3–1–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–1079; FRL–9331–8]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiamethoxam in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 2, 2012. Objections and requests for hearings must be received on or before May 1, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–1079. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Gene Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0235; email address: *Benbow.Gene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–1079 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 1, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–1079, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL–8884–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7805) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.565 be amended by establishing tolerances for residues of the insecticide thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine and its metabolite, *N*-[(2-chloro-thiazol-5-yl)methyl]-*N'*-methyl-*N''*-nitro-guanidine], in or on: buckwheat, grain at 0.02 per million (ppm); buckwheat, forage at 0.50 ppm; buckwheat, hay at 0.02 ppm; buckwheat, straw at 0.02 ppm; oat, grain at 0.02 ppm; oat, forage at 0.50 ppm, oat, hay at 0.02 ppm; oat, straw at 0.02 ppm; millet, pearl, grain at 0.02 ppm; millet, pearl, forage at 0.02 ppm; millet, pearl, stover at 0.02 ppm; millet, proso, grain at 0.02 ppm; millet, proso, forage at 0.02 ppm; millet, proso, stover at 0.02 ppm; millet, proso, straw at 0.02 ppm; rye, grain at 0.02 ppm; rye, forage at 0.50 ppm; rye, straw at 0.02 ppm; teosinte, grain at 0.02 ppm; teosinte, forage at 0.10 ppm; teosinte, stover at 0.05 ppm; triticale, grain at 0.02 ppm; triticale, forage at 0.05 ppm; triticale, hay at 0.02 ppm; triticale, straw at 0.02 ppm; wild rice, grain at 0.02 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiamethoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiamethoxam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Thiamethoxam shows toxicological effects primarily in the liver, kidney, testes, and hematopoietic system. In addition, developmental neurological effects were observed in rats. This developmental effect is being used to assess risks associated with acute exposures to thiamethoxam, and the liver and testicular effects are the basis for assessing longer term exposures. Although thiamethoxam causes liver tumors in mice, the Agency has classified thiamethoxam as ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer.

Specific information on the studies received and the nature of the adverse effects caused by thiamethoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in section 4.5.1 in the document ''Thiamethoxam—Human Health Risk Assessement for Crop Group 15 (including buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale) and Crop Group 16 Commodities (forage, fodder and straw of cereal grains group)'' in docket ID number EPA–HQ–OPP–2010–1079 at *http://www.regulations.gov*.

Thiamethoxam produces a metabolite known as CGA–322704 (referred to in the remainder of this rule as clothianidin). Clothianidin is also registered as a pesticide. While some of the toxic effects observed following testing with thiamethoxam and clothianidin are similar, the available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately. A separate risk assessment of clothianidin has been completed in conjunction with the registration of clothianidin. The most recent assessment, which provides details regarding the toxicology of clothianidin, is available in the docket EPA–HQ–OPP–2008–0945, at *http://www.regulations.gov*. Refer to the document ''Clothianidin: Human Health Risk Assessment for the Requested New Use on Mustard Seen as well as New Uses of Thiamethoxam on Peanuts, Alfalfa, in Food-Handling Establishments, and as a Seed Treatment for Cereal Grains.''

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (U/S F) are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for thiamethoxam used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations including infants and children).	NOAEL = 34.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1	Acute RfD = 0.35 mg/kg/day. aPAD = 0.35 mg/kg/day	Rat Developmental Neurotoxicity study. LOAEL = 298.7 mg/kg/day based on delayed sexual maturation in male pups, and reduced brain morphometric measurements.
Chronic dietary (All populations including infants and children).	NOAEL = 1.2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1	Chronic RfD = 0.012 mg/kg/day. cPAD = 0.012 mg/kg/day.	2-Generation reproduction study. 1. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study. 2. LOAEL = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F_1 males.
Incidental oral (all durations).	NOAEL = 8.23 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1	MOE = 100 (residential)	90-day Dog study. LOAEL = 32 (males) 33.9 (females) mg/kg/day based on slightly prolonged prothrombin times and decreased plasma albumin and A/G ratio (both sexes); decreased calcium levels and ovary weights and delayed maturation in the ovaries (females); decreased cholesterol and phospholipid levels, testis weights, spermatogenesis, and spermatic giant cells in testes (males).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal (all durations) (Adults).	Oral study NOAEL = 1.2 mg/kg/day (dermal absorption rate = 5%) UF_A = 10x UF_H = 10x FQPA SF = 1	MOE = 100 (residential)	2-Generation reproduction study. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study. LOAEL = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F_1 males.
Dermal (all durations) (infants/children 1–6 yrs).	Dermal study NOAEL = 60 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1	MOE = 100 (residential)	Rat 28-Day Dermal Toxicity Study. LOAEL = 250 (females) mg/kg/day based on increased plasma glucose, triglyceride levels, and alkaline phosphatase activity and inflammatory cell infiltration in the liver and necrosis of single hepatocytes in females.
Inhalation (all durations)	Oral study NOAEL = 1.2 mg/kg/day (inhalation absorption rate = 100% of oral absorption) UF_A = 10x UF_H = 10x FQPA SF = 1	MOE = 100 (residential)	2-Generation reproduction study. LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F_1 generation males. 2-Generation reproduction study. LOAEL = 3 (males), not determined (females) mg/kg/day based on sperm abnormalities in F_1 males.

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. mg/kg/day = milligrams/kilogram/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing thiamethoxam tolerances in 40 CFR 180.565. EPA assessed dietary exposures from thiamethoxam in food as follows:

For both acute and chronic exposure assessments for thiamethoxam, EPA combined residues of clothianidin coming from thiamethoxam with residues of thiamethoxam *per se.* As discussed in this unit, thiamethoxam's major metabolite is CGA–322704, which is also the registered active ingredient in clothianidin. Available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately; however, these exposure assessments for this action incorporated the total residue of thiamethoxam and clothianidin from use of thiamethoxam because the total residue for each commodity for which thiamethoxam has a tolerance has not been separated between thiamethoxam and its clothianidin metabolite. The combining of these residues, as was done in this assessment, results in highly conservative estimates of dietary exposure and risk. A separate assessment was done for clothianidin. The clothianidin assessment included clothianidin residues from use of clothianidin as a pesticide and clothianidin residues from use of thiamethoxam on those commodities for which the pesticide clothianidin does not have a tolerance. As to these commodities, EPA has separated total residues between thiamethoxam and clothianidin.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for thiamethoxam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). For residue levels in food, EPA assumed tolerance level residues of thiamethoxam and clothianidin. It was further assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. For residue levels in food, EPA assumed tolerance level and/or anticipated residues (averages) from field trial data. It was again assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated.

A complete listing of the inputs used in these assessments can be found in the following documents: ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration on Crop Group 15/16 Commodities'' available in the docket EPA–HQ–OPP–2010–1079, at *http://www.regulations.gov;* and ''Clothianidin—Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments to Evaluate Requested Uses on Mustard Seed and Requested uses of Thiamethoxam on Peanuts, in Food-Handling Establishments, and as a Seed Treatment for Cereal Grains,'' available in the docket EPA–HQ–OPP–2008–0945, at *http://www.regulations.gov.*

iii. *Cancer.* EPA concluded that thiamethoxam is ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse, and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of

action for cancer and thus a separate exposure assessment pertaining to cancer risk is not necessary. Because clothianidin is not expected to pose a cancer risk, a quantitative dietary exposure assessment for the purposes of assessing cancer risk was not conducted.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thiamethoxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiamethoxam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Tier 1 Rice Model for surface water and the Screening Concentration in Ground Water (SCI–GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 0.13177 ppm for surface water and 0.00466 ppm for ground water. The chronic exposure for surface water and ground water is estimated to be 0.01131 ppm and 0.00466 ppm respectively. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

Since clothianidin is not a significant degradate of thiamethoxam in surface water or ground water sources of drinking water, it was not included in the EDWCs for the thiamethoxam dietary assessment. For the clothianidin assessments, the EDWC value of 0.0724 ppm for clothianidin was incorporated into the acute and chronic dietary assessments.

A complete listing of the inputs used in these assessments can be found in the following documents: ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration on Crop Group 15/16 Commodities'' available in the docket EPA–HQ–OPP–2010–1079, at *http://www.regulations.gov;* and ''Tier I Drinking Water Exposure Assessment for the Section 3 New Uses of Clothianidin on Rice and Leafy Vegetables,'' available in the docket EPA–HQ–OPP–2008–0945, at *http://www.regulations.gov.*

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Thiamethoxam is currently registered for the following uses that could result in residential exposures: Turfgrass on golf courses, residential lawns, commercial grounds, parks, playgrounds, athletic fields, landscapes, interiorscapes, sod farms, and indoor crack and crevice or spot treatments to control insects in residential settings. EPA assessed residential exposure using the assumption that thiamethoxam is applied by commercial applicators only. However, entering areas previously treated with thiamethoxam could lead to exposures for adults and children. As a result, risk assessments have been completed for postapplication scenarios.

Short-term postapplication exposures (1 to 30 days of continuous exposure) may occur as a result of activities on treated turf or entering indoor areas previously treated with a thiamethoxam indoor crack and crevice product. EPA combined all non-dietary sources of children's post application exposure to obtain an estimate of potential combined exposure. These scenarios consisted of dermal postapplication exposure and oral (hand-to-mouth) exposures for children 3 to 6 years of age.

A complete listing of the inputs used in these assessments can be found in the document ''Thiamethoxam—Human Health Risk Assessment for Crop Group 15 (including buckwheat, pearl millet, proso millet, oats, rye, teosinte, triticale) and Crop Group 16 Commodities (forage, fodder and straw of cereal grains group)'' in docket ID number EPA–HQ–OPP–2010–1079 at *http://www.regulations.gov.* Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Thiamethoxam is a member of the neonicotinoid class of pesticides and produces, as a metabolite, another neonicotinoid, clothianidin. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for thiamethoxam is based on unrelated effects in mammals, including effects on the liver, kidney, testes, and hematopoietic system. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidacloprid).

Thus, EPA has not found thiamethoxam or clothianidin to share a common mechanism of toxicity with any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiamethoxam and clothianidin do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of

safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the developmental studies, there is no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure to thiamethoxam. The developmental NOAELs are either higher than or equal to the maternal NOAELs. The toxicological effects in fetuses do not appear to be any more severe than those in the dams or does. In the rat developmental neurotoxicity study, there was no quantitative evidence of increased susceptibility; however, there was increased qualitative susceptibility because the effects in the pups (reduced brain weight and significant changes in brain morphometric measurements) were considered to be more severe than findings in the dams (decreased body weight gain and food consumption).

There is evidence of increased quantitative susceptibility for male pups in both 2-generation reproductive studies. In one study, there are no toxicological effects in the dams; whereas, for the pups, reduced bodyweights are observed at the highest dose level, starting on day 14 of lactation. This contributes to an overall decrease in bodyweight gain during the entire lactation period. The reproductive effects in males appear in the F_1 generation in the form of increased incidence and severity of testicular tubular atrophy (see developmental/reproductive section). These data are considered to be evidence of increased quantitative susceptibility for male pups (increased incidence of testicular tubular atrophy at 1.8 mg/kg/day) when compared to the parents (hyaline changes in renal tubules at 61 mg/kg/day; NOAEL is 1.8 mg/kg/day).

In a more recent 2-generation reproduction study, the most sensitive effect was sperm abnormalities at 3 mg/kg/day (the NOAEL is 1.2 mg/kg/day) in the F_1 males. This study also indicates increased susceptibility for the offspring for this effect.

Although there is evidence of increased quantitative susceptibility for male pups in both reproductive studies, NOAELs and LOAELs were established in these studies and the Agency selected the NOAEL for testicular effects in F_1 pups as the basis for risk assessment. The Agency has confidence that the NOAEL selected for risk assessment is protective of the most sensitive effect (testicular) for the most sensitive subgroup (pups) observed in the toxicological database.

3. *Conclusion.* i. In the final rule published in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL–7689–7), EPA had previously determined that the FQPA SF should be retained at 10X for thiamethoxam, based on the following factors: Effects on endocrine organs observed across species; significant decrease in alanine amino transferase levels in companion animal studies and in dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetylcholine receptors of the insect's nervous system); the transient clinical signs of neurotoxicity in several studies across species; and the suggestive evidence of increased quantitative susceptibility in the rat reproduction study. Since that determination, EPA has received and reviewed a developmental neurotoxicity (DNT) study in rats, and an additional reproduction study in rats. Taking the results of these studies into account, as well as the rest of the data on thiamethoxam, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X (June 23, 2010, 75 FR 35653; FRL–8830–4); (June 22, 2007, 72 FR 34401). That decision is based on the following findings:

a. The toxicity database for thiamethoxam is largely complete, including acceptable/guideline developmental toxicity, 2-generation reproduction, and DNT studies designed to detect adverse effects on the developing organism, which could result from the mechanism that may have produced the decreased alanine amino transferase levels. The available data for thiamethoxam show the potential for immunotoxic effects. In the subchronic dog study, leukopenia (decreased white blood cells) was observed in females only, at the highest dose tested (HDT) of 50 mg/kg/day; the NOAEL for this effect was 34 mg/kg/day. The overall study NOAEL was 9.3 mg/kg/day in females (8.2 mg/kg/day in males) based on hematology and other clinical chemistry findings at the LOAEL of 34 mg/kg/day (32 mg/kg/day in males). In the subchronic mouse study, decreased spleen weights were observed in females at 626 mg/kg/day; the NOAEL for this effect was the next lowest dose of 231 mg/kg/day. The overall study NOAEL was 1.4 mg/kg/day (males) based on increased hepatocyte hypertrophy observed at the LOAEL of 14.3 mg/kg/day. The decreased absolute spleen weights were considered to be treatment related, but were not statistically significant at 626 mg/kg/day or at the HDT of 1,163 mg/kg/day. Since spleen weights were not decreased relative to body weights, the absolute decreases may have been related to the decreases in body weight gain observed at higher doses. Overall, the Agency has a low concern for the potential for immunotoxicity related to these effects for the following reasons: In general, the Agency does not consider alterations in hematology parameters alone to be a significant indication of potential immunotoxicity. In the case of thiamethoxam, high-dose females in the subchronic dog study had slight microcytic anemia as well as leukopenia characterized by reductions in neutrophils, lymphocytes and monocytes; the leukopenia was considered to be related to the anemic response to exposure. Further, endpoints and doses selected for risk assessment are protective of the observed effects on hematology. Spleen weight decreases, while considered treatment-related, were associated with decreases in body weight gain, and were not statistically significant. In addition, spleen weight changes occurred only at very high doses, more than 70 times higher than the doses selected for risk assessment.

In addition to the previous considerations, a 28-day immunotoxicity study in female mice was recently received and has undergone a preliminary review. There were no immunotoxic effects observed at doses exceeding the limit dose of 1,000 mg/kg/day.

b. For the reasons discussed in Unit III.D.2., there is low concern for an increased susceptibility in the young.

c. Although there is evidence of neurotoxicity after acute exposure to thiamethoxam at doses of 500 mg/kg/day including drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength, no evidence of neuropathology was observed. These effects occurred at doses at least 14-fold and 416-fold higher than the doses used for the acute, and chronic risk assessments, respectively; thus, there is low concern for these effects since it is expected that the doses used for regulatory purposes would be protective of the effects noted at much higher doses.

In the developmental neurotoxicity study (DNT), there was no evidence of neurotoxicity in the dams exposed up to 298.7 mg/kg/day; a dose that was associated with decreases in body weight gain and food consumption. In pups exposed to 298.7 mg/kg/day, there

were significant reductions in absolute brain weight and size (i.e., length and width of the cerebellum was less in males on day 12, and there were significant decreases in Level 3–5 measurements in males and in Level 4–5 measurements in females on day 63). However, there is low concern for this increased qualitative susceptibility observed in the DNT study because the doses and endpoints selected for risk assessment are protective of the effects in the offspring. As noted previously, for risk assessment the Agency selected the NOAEL for testicular effects in F_1 pups based on two reproductive toxicity studies to be protective of all sensitive subpopulations.

d. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using tolerance-level and/or anticipated residues that are based on reliable field trial data observed in the thiamethoxam field trials. Although there is available information indicating that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately, the residues of each have been combined in these assessments to ensure that the estimated exposures of thiamethoxam do not underestimate actual potential thiamethoxam exposures. An assumption of 100 percent crop treated (PCT) was made for all foods evaluated in the assessments. For the acute and chronic assessments, the EDWCs of 131.77 parts per billion (ppb) and 11.3 ppb, respectively, were used to estimate exposure via drinking water. Compared to the results from small scale prospective ground water studies where the maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for clothianidin, the modeled estimates are protective of what actual exposures are likely to be. EPA used similarly conservative (protective) assumptions to assess postapplication exposure to children and adults including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

ii. In the final rule published in the **Federal Register** of February 6, 2008 (73 FR 6851) (FRL–8346–9), EPA had previously determined that the FQPA SF for clothianidin should be retained at 10X because EPA had required the submission of a developmental immunotoxicity study to address the combination of evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin database, and evidence showing that juvenile rats in the 2-generation reproduction study appear to be more susceptible to these potential immunotoxic effects. In the absence of a developmental immunotoxicity study, EPA concluded that there was sufficient uncertainty regarding immunotoxic effects in the young that the 10X FQPA factor should be retained as a database uncertainty factor.

Since that determination, EPA has received and reviewed an acceptable/guideline developmental immunotoxicity study, which demonstrated no treatment-related effects. Taking the results of this study into account, as well as the rest of the data on clothianidin, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for clothianidin were reduced to 1X (February 11, 2011, 76 FR 7712) (FRL–8858–3). That decision is based on the following findings:

a. The toxicity database for clothianidin is complete. As noted, the prior data gap concerning developmental immunotoxicity has been addressed by the submission of an acceptable developmental immunotoxicity study.

b. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for prenatal and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility; therefore, there are no residual concerns regarding effects in the young.

c. While the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL and LOAEL have been selected for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for prenatal and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

d. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on assumptions that were judged to be highly conservative and health-protective for all durations and population subgroups, including tolerance-level residues, adjustment factors from metabolite data, empirical processing factors, and 100 PCT for all commodities. Additionally, EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children and adults as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thiamethoxam will occupy 9.5% of the aPAD for All infants (<1 year), the population group receiving the greatest exposure. Acute dietary exposure from food and water to clothianidin is estimated to occupy 23% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* In examining chronic aggregate risk, EPA has assumed that the only pathway of exposure relevant to that time frame is dietary exposure. Using this assumption for chronic exposure, EPA has concluded that chronic exposure to thiamethoxam from food and water will utilize 43% of the cPAD for Children 1 to 2 years old, the population group receiving the greatest exposure. Chronic exposure to clothianidin from food and water will utilize 19% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water

(considered to be a background exposure level). Thiamethoxam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to thiamethoxam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for thiamethoxam result in aggregate MOEs of: 370 for the general U.S. population; 490 for all infants; 440 for children 1 to 2 years; 450 for children 3 to 5 years; 370 for children 6 to 12 years; 380 for youth 13 to 19 years, adults 20 to 49 years, adults 50+ years, and females 13 to 49 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for clothianidin result in aggregate MOEs of: 1,200 for the general U.S. population; 480 for all infants (<1 year); 370 for children 1 to 2 years; 490 for children 3 to 5 years; 1,000 for children 6 to 12 years; 1,400 for youth 13 to 19 years, adults 20–49 years, and females 13 to 49 years; and 1,300 for adults 50+ years. Because EPA's level of concern for clothianidin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Thiamethoxam is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to thiamethoxam.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures for thiamethoxam result in aggregate MOEs of: 370 for the general U.S. population; 540 for all infants (<1 year); 470 for children 1 to 2 years; 490 for children 3 to 5 years; 370 for children 6 to 12 years; 380 for youth 13 to 19 years, adults 20 to 49 years, adults 50+ years, and females 13 to 49 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

Using the exposure assumptions described in this unit for intermediate exposures, EPA has concluded the combined intermediate food, water, and residential exposures for clothianidin result in aggregate MOEs of: 1,200 for the general U.S. population; 480 for all infants (<1 year); 370 for children 1 to 2 years; 490 for children 3 to 5 years; 1,000 for children 6 to 12 years; 1,400 for youth 13 to 19 years, adults 20 to 49 years, and females 13 to 49 years; and 1,300 for adults 50+ years. Because EPA's level of concern for clothianidin is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified thiamethoxam as not likely to be a human carcinogen based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. Therefore, thiamethoxam is not expected to pose a cancer risk. Clothianidin has been classified as ''not likely to be a human carcinogen'' and is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to thiamethoxam or clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The High Production Liquid Chromatography (HPLC) Method AG–675 with ultraviolet (UV) or Mass Spectrometry (MS) detection was previously submitted in conjunction with thiamethoxam petitions. Method AG–675 has been determined to be adequate for enforcing the tolerance expression for residues of thiamethoxam and CGA–322704 in crop and livestock commodities. Syngenta Crop Protection, Inc., has submitted a revised Method AG–675, i.e., Method GRM.009.04A. The full extraction steps for plant and livestock commodities, including the microwave extraction step for liver, have been incorporated. The limits of quantitation (LOQs) of Method GRM.009.04A have been established at 0.01 ppm each for residues of thiamethoxam, CGA–322704 and CGA–265307. Method validation data are available for Method GRM.009.04A.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

EPA is increasing the barley grain tolerance to 0.4 ppm in order to harmonize with the Codex MRL of 0.4 ppm. The MRL expressions continue to remain different, as the Codex MRL is for the parent compound only.

C. Revisions to Petitioned-For Tolerances

Although the petitioner sought tolerances for many of the commodities in Crop Groups 15 and 16, the petitioner did not request crop group tolerances. EPA has determined that a tolerance for either Crop Group 15 or Crop Group 16 commodities is not appropriate except for Crop Group 15 grains (except barley), because the use pattern is not the same for all Crop Group 15 commodities. Specifically, there is a foliar use on barley and there are much higher tolerances for barley hay and straw associated with this foliar use. It is for similar reasons that a Crop Group 16 tolerance would not be appropriate.

In addition, there are also significant differences in the tolerances for the different cereal forages, i.e., wheat forage at 0.5 ppm, corn forage at 0.10 ppm, and sorghum forage at 0.02 ppm. Therefore, tolerances for each individual commodity have been established by translating residue data from the most appropriate representative commodity, except for grains which all have the same tolerance (excluding barley). Tolerances are not required for triticale and wild rice because these commodities are covered by the wheat and rice tolerances, as

specified in 40 CFR 180.1. Tolerances are also not needed for teosinte forage and stover as these are not considered significant livestock feed items and are not consumed by humans.

V. Conclusion

Therefore, tolerances are established for residues of thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine and its metabolite, *N*-[(2-chloro-thiazol-5-yl)methyl]-*N′*-methyl-*N″*-nitro-guanidine, in or on barley, grain at 0.4 ppm; buckwheat, forage at 0.50 ppm; buckwheat, hay at 0.02 ppm; buckwheat, straw at 0.02 ppm; grain, cereal, group 15, except barley at 0.02 ppm; oat, forage at 0.50 ppm, oat, hay at 0.02 ppm; oat, straw at 0.02 ppm; millet, pearl, forage at 0.02 ppm; millet, pearl, stover at 0.02 ppm; millet, proso, forage at 0.02 ppm; millet, proso, stover at 0.02 ppm; millet, proso, straw at 0.02 ppm; rye, forage at 0.50 ppm; rye, straw at 0.02 ppm. Tolerances are revoked for corn, field, grain; corn, pop, grain; rice, grain; sorghum, grain; wheat, grain. These tolerances are no longer needed, since residues on these commodities will be covered by the crop group 15 tolerances being established in this rule.

In addition, administrative corrections are being made to the existing tolerances for grain, aspirated fractions and soybean, hulls, as follows: The tolerance for grain, aspirated fractions at 0.08 ppm is being corrected to grain, aspirated fractions at 2.0 ppm; the tolerance for soybean, hulls at 2.0 ppm is being corrected to soybean, hulls at 0.08 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.565 paragraph (a) is revised to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide thiamethoxam, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified below is to be determined by measuring only thiamethoxam 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite CGA–322704 N-[(2-chloro-thiazol-5-yl)methyl]-N′-methyl-N″-nitro-guanidine, calculated as the stoichiometric equivalent of thiamethoxam, in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.12
Almond, hulls	1.2
Artichoke, globe	0.45
Avocado	0.40
Barley, grain	0.4
Barley, hay	0.40
Barley, straw	0.40
Bean, succulent	0.02
Berry, low growing, subgroup 13–07G, except cranberry	0.30
Borage, seed	0.02
Brassica, head and stem, subgroup 5–A	4.5
Brassica, leafy greens, subgroup 5–B	3.0
Buckwheat, forage	0.50
Buckwheat, hay	0.02
Buckwheat, straw	0.02
Bushberry subgroup 13–07B, except lingonberry and blueberry, lowbush	0.20
Canistel	0.40
Canola, seed	0.02
Cattle, meat	0.02

Commodity	Parts per million
Cattle, meat byproducts	0.04
Citrus, dried pulp	0.60
Coffee, bean, green [1]	0.05
Corn, field, stover	0.05
Corn, pop, forage	0.10
Corn, pop, stover	0.05
Corn, sweet, forage	0.10
Corn, sweet, kernel plus cob with husks removed	0.02
Corn, sweet, stover	0.05
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.10
Crambe, seed	0.02
Cranberry	0.02
Flax, seed	0.02
Food commodities and feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments	0.02
Fruit, citrus, group 10	0.40
Fruit, pome, group 11	0.2
Fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwifruit	0.20
Fruit, stone, group 12	0.5
Goat, meat	0.02
Goat, meat byproducts	0.04
Grain, aspirated fractions	2.0
Grain, cereal, group 15, except barley	0.02
Grape, raisin	0.30
Hog, meat	0.02
Hog, meat byproducts	0.02
Hop, dried cones	0.10
Horse, meat	0.02
Horse, meat byproducts	0.04
Mango	0.40
Milk	0.02
Millet, pearl, forage	0.02
Millet, pearl, stover	0.02
Millet, proso, forage	0.02
Millet, proso, stover	0.02
Millet, proso, straw	0.02
Oat, forage	0.50
Oat, hay	0.02
Oat, straw	0.02
Peanut	0.05
Peanut, hay	0.25
Peanut, meal	0.15
Peppermint, tops	1.5
Pistachio	0.02
Potato	0.25
Radish, tops	0.80
Rapeseed, seed	0.02
Rye, forage	0.50
Rye, straw	0.02
Sapodilla	0.40
Sapote, black	0.40
Sapote, mamey	0.40
Sheep, meat	0.02
Sheep, meat byproducts	0.04
Sorghum, forage	0.02
Sorghum, grain, stover	0.02
Soybean, hulls	0.08
Spearmint, tops	1.5
Star apple	0.40
Sunflower	0.02
Tomato, paste	0.80
Vegetable, cucurbit, group 9	0.2
Vegetable, fruiting, group 8	0.25
Vegetable, leafy, except brassica, group 4	4.0
Vegetable, legume, group 6	0.02
Vegetable, root, subgroup 1A	0.05
Vegetable, tuberous and corm, except potato, subgroup 1D	0.02
Wheat, forage	0.50
Wheat, hay	0.02
Wheat, straw	0.02

[1] There are no U.S. registrations as of September 17, 2003.

* * * * *

[FR Doc. 2012–4983 Filed 3–1–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0524; FRL–9337–9]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 2, 2012. Objections and requests for hearings must be received on or before May 1, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0524. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8072; email address: *benbow.bethany@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation

MDH Minnesota Department of Health

HEALTH RISK ASSESSMENT UNIT

Thiamethoxam and Drinking Water

Summary

Thiamethoxam is a pesticide used at a household and industrial level on crops, ornamental plants, yards, and turf. Thiamethoxam has been detected in Minnesota groundwater and surface water at levels below the guidance value developed by MDH. People can be exposed to thiamethoxam by eating or drinking contaminated food or water or when spending time in an area that was recently treated with thiamethoxam. Exposure to high levels of thiamethoxam over time has been shown to cause adverse developmental, male and female reproductive, and liver effects in animal studies.[1] Minnesotans are not likely to experience health effects from the levels of thiamethoxam found in the environment.

Thiamethoxam

Thiamethoxam is a neonicotinoid pesticide that helps protect against sucking and chewing insects—like aphids, thrips, and beetles. This pesticide is used on a variety of crops, including corn and soybeans. Thiamethoxam is also used to protect livestock pens, poultry houses, sod farms, golf courses, lawns, household plants, and Christmas trees.[2] Thiamethoxam is also used to treat seed and to preserve wood. Over the past decade, the use of thiamethoxam has increased dramatically throughout the Midwest.[3]

Thiamethoxam in Minnesota Waters

The Minnesota Department of Agriculture (MDA) monitors surface water, groundwater, and drinking water for many pesticides, including thiamethoxam. In 2014, MDA found thiamethoxam in five percent of groundwater samples and 11 percent of surface water samples. They did not detect thiamethoxam in drinking water. The maximum level of thiamethoxam MDA detected in groundwater was 1.365 parts per billion (ppb) and 0.223 ppb in surface water.[4]

MDH Guidance Value

[redacted].

Potential Exposure to Thiamethoxam

People can be exposed to thiamethoxam through drinking contaminated water or eating contaminated food. The EPA has set limits on the amount of thiamethoxam and clothianidin (a chemical produced when thiamethoxam breaks down) residues allowed in various food products to reduce this exposure. People spending time in an area recently treated with thiamethoxam, applying thiamethoxam, or working with thiamethoxam-coated seeds can be exposed through skin contact or by breathing it in.

Potential Health Effects

Animal testing showed that short-term exposure to high levels of thiamethoxam caused adverse developmental, female reproductive, and liver effects. Animals exposed to thiamethoxam for longer durations, but at lower doses, experienced changes to the male reproductive system.

Using Thiamethoxam Safely

People who use thiamethoxam should follow product label directions. Wash your hands thoroughly with soap and water after handling thiamethoxam and before eating or drinking. People and pets should not re-enter an area treated with thiamethoxam until the product has dried completely.

Thiamethoxam in the Environment

Thiamethoxam enters the environment through a variety of agricultural and residential uses including coated seeds, spraying, and aerial application. Thiamethoxam can be carried into surface water by storm water runoff, soil erosion, or spray drift. Thiamethoxam breaks down in less than 60 days in the environment. One of the chemicals thiamethoxam breaks down into is another pesticide called clothianidin, which takes years to break down in soil.[5] These pesticides move quickly through soil and are the most frequently detected neonicotinoids in Minnesota. [6]

Potential Environmental Impacts of Thiamethoxam

Because thiamethoxam is an insecticide, insects and aquatic invertebrates are most likely to be affected by low levels of thiamethoxam in the environment. Minnesota does not have an aquatic life water quality standard for thiamethoxam. The highest measured concentration of thiamethoxam in Minnesota surface waters is below the US Environmental Protection Agency's (US EPA) current benchmark values. Organisms living on land are also affected and it is likely that thiamethoxam harms and kills insects that pollinate plants, like bees.[7]

Health Risk Assessment Unit

The MDH Health Risk Assessment Unit evaluates the health risks from contaminants in groundwater. MDH works in collaboration with the Minnesota Pollution Control Agency and the Minnesota Department of Agriculture to understand the occurrence and environmental effects of contaminants in water.

References

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October 2016

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